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EXAMINER	
SHEINBERG, MONIKA B	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/667,188	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Appellant's Brief

In view of the appeal brief filed on June 30, 2003, PROSECUTION IS HEREBY REOPENED with the instant Non-Final Action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

- Claims 1, 2 and 11-15 are pending.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 101/112

- *Utility Guidelines*

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 USC § 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicants assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

- 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- The rejection of claims 1, 2 and 11- 15 is reiterated and maintained under 35 U.S.C. 101 because the claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (page 38, lines 4- 6), determining whether a plant contains a mutation (page 38, lines 19-20), and acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function (page 15, lines 20-24). These are non-specific uses that are applicable to polynucleotides in general and not particular or specific to the polynucleotide claimed. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial

asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

- The rejection of claims 1, 2 and 11- 15 is reiterated and maintained under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments
Overview: Utility/Enablement

- The applicant's arguments have been fully considered and have not been found persuasive. The current USPTO utility guidelines state (*emphasis added*):

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes chromosome markers, or forensic or diagnostic markers. Therefore the credibility of such an assertion would not be questioned, although such a use might fail the- specific and substantial tests (see below).

"Specific Utility" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. ' 10 1.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility."

D. A method of making a material that itself has no specific, substantial, and credible utility. '

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial asserted utility would be considered to be met.

A "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. 'Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

- In summary applicants argue that utility requirement has been met since "they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, the ability to identify the presence or absence of a polymorphism in a population of wheat plants" (p. 3, 1st paragraph); other utilities of the claimed nucleic acid argued throughout the response are identifying promoters, use as sense or antisense inhibitors,

use as probes or as a source of primers. In addition, applicants state that the public recognizes such utilities of the claimed nucleic acid and ESTs because of the occurrence of the "growth of a multi-mullion dollar industry in the Unites States" (p. 10, 2nd paragraph) proving their "commercial value" (3rd paragraph). Applicants' arguments are not convincing because the rejection is based upon the asserted utilities being general utilities rather than being specific and substantial as is required by the utility guidelines. There is no question that the disclosed nucleic acid could be used as a probe to detect itself. However, the detection of this polynucleotide has no real world use because the function of the protein encoded by the nucleic acid has not been described nor has the polynucleotide been associated with a disease or some other immediately useful property. Therefore using the nucleic acid to detect a polymorphism in a wheat plant is not substantial for example because no "real world use" has been established for detecting the polymorphism in a wheat plant. A correlation between the polymorphism and a specific disease that one of skill in the art would want to detect would be an example of a substantial utility. No such correlation exists in the instant case.

The utilities asserted for the invention in the specification and reiterated in the applicant's arguments are not specific because they are applicable to nucleic acids in general and not only to the claimed invention in particular. The utility guidelines state that a specific utility must be specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. "For example, a claim to a polynucleotide whose use is disclosed simply as a 'gene probe' or 'chromosome marker' would not be considered to be specific in the absence of a disclosure of a specific DNA target" (underlined in the MPEP exert above). Any nucleic acid molecule from any source can be used to determine the presence of polymorphisms, isolate specific promoter sequences, and obtain nucleic acid homologues, and therefore the asserted utilities are non-specific. The asserted non-specific utilities do not take advantage of the specific properties of the nucleic acid sequence of SEQ ID NO: 1. In addition, the asserted utilities for the nucleic acid of SEQ ID NO: 1 are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be

identified as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific, substantial, or well-established utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility.

Utility

- In paragraph 2 of page 4 the applicants traverse the examiner's assertion that the asserted utilities of the claimed invention is not supported by either a specific or substantial utility. The applicants assert that the examiners' analysis

"misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of 'practical utility' developed by the courts after *Brenner v. Manson*. The 'threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit.' *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 USPQ2d 1700, 1702 (Fed. Cir. 1999) *citing Brenner v. Manson*, 383 US 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 USC § 101"

This argument was thoroughly reviewed but not found persuasive because applicants have not disclosed an identifiable benefit wherein the one identifiable benefit has a real world or well established utility (readily available or apparent).

- In the bridging paragraph of pages 4-5 and paragraph 2 of page 5, applicants argue "[a] corollary to this test for utility is that the invention must not be 'totally incapable of achieving a useful result,' *i.e.*, the utility must not be incredible or unbelievable[;]" stating that identifiable benefits such as identifying promoters involved in gene regulation, for determining whether a plant contains a mutation, and for use acting as molecular tags to isolate genes, map genes, and determine gene function satisfy 35 USC 101. This argument was thoroughly reviewed but not found persuasive for reasons described below. In regards to identifying promoters involved in gene regulation, further experimentation is required because no evidence is present in the specification that suggests or proves that the nucleic acid of the instant invention will identify a promoter involved in gene regulation. With respect to determining whether a plant contains a mutation, there exists a requirement for further experimentation to determine if the mutation is causing aberrant function or disease. With respect to use as molecular tags, there exists a requirement for further experimentation to determine if that which is tagged has any function or

characteristic of relevant value to biological processes causing aberrant function or disease. Furthermore, the rejection has not questioned the credibility of the asserted uses.

Specific Utility

- In paragraph 3 of page 5, (footnote 1); applicants argue that "it is irrelevant whether the corresponding mRNA or polypeptide have utility because applicants are not relying on utility of the mRNA or polypeptide to establish utility for the claimed nucleic acid molecules". However, please note that 'nucleic acid molecules' are inclusive of mRNA, and no specific or substantial utility has been correlated to the nucleic acid molecule be it mRNA or not. Applicants further argue the nucleic acid can be utilized for screening compounds such as herbicides while they act as sense or antisense inhibitors. This argument was thoroughly reviewed but not found persuasive because the possibility of whether or not the sense or antisense will actually inhibit anything is uncertain and unpredictable, let alone be involved in herbicidal processes. The specification provides no evidence to suggest this nucleic acid is even associated with genes involved in the herbicidal processes to be useful in screening for herbicides.

- In the bridging paragraph of pages 5-6; other utilities of the claimed nucleic acid molecule argued by the applicant are for measuring the level of mRNA and use as molecular markers. With respect to the measurement of mRNA, applicant argues that "it is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray without characterizing each and every target mRNA. [... therefore] it is a **use** of the claimed nucleic acid molecules in a real world context" (footnote 3). This argument was thoroughly reviewed but not found persuasive because the specification's only disclosure regarding microarrays is found on pages 55-57. That disclosure states only that microarrays can be used for "monitoring of plant gene expression [which] may be utilized to measure gene-specific hybridization targets. This 'chip'-based approach involves using microarrays of nucleic acid molecules as gene-specific hybridization targets to quantitatively measure expression of the corresponding plant genes" (p. 55 last paragraph). Applicants assert that the use of microarrays is to monitor plant gene expression in research related to "traits of interest, e.g. drought stress" (footnote 4) however this

argument is not found persuasive because the mere use of the claimed polynucleotides as a component of a microarray would not satisfy § 101's utility requirement. The attachment of the claimed nucleic acid molecule (or part of it) to a solid substrate in combination with other nucleic acid molecules to monitor the gene expression of an encoded protein (that has not yet been correlated to SEQ ID NO: 1), does not allow a skilled artisan to use such data relating to the unknown protein expression in any practical way. The specification simply provides no guidance regarding what the expression information derived from such a microarray would mean.

- *Polymorphism detection*

- In the 2nd- 3rd paragraphs of page 6; applicants argue the nucleic acid can be utilized for identifying the presence or absence of a polymorphism and thus is a specific and substantial utility. In addition, the analogy is made that the "disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope". This argument was thoroughly reviewed but not found persuasive because the nucleic acid of the present invention is not analogous to a microscope. A microscope has a specific and substantial utility of magnifying images to allow the visualization of- items too small to be seen by the unaided eye. This utility is specific for a microscope and is based on the physical structure of the lenses and mirrors present within the microscope. Applicants are effectively arguing that a nucleic acid and microscope are analogous because they can be used as a research tool. However, the claimed nuclei acid can only be used to detect sequences that themselves have no specific and substantial utility. This is analogous to the disclosure of a microscope containing a slide which contains an unknown smear of matter and providing claims to the unknown smear of matter. In regards to SEQ ID NO: 1, it is a fragment of larger sequence that has no described function that would allow one to identify a specific plant protein product as recited by the claims. With respect to the detection of polymorphisms being a specific and substantial utility, the argument is not convincing because the detection of a polymorphisms is not useful until the polymorphisms is associated with a disease or other specific characteristic of interest to the public.

- In the bridging paragraph of pages 6-7 and paragraph 2 of page 7; applicants asserts the "[u]se of the claimed nucleic acid molecules to detect the presence or absence of a polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of gas – such use determines information about the gas, not the gas chromatograph." This is not found to be persuasive because the gas chromatograph is an apparatus that as the microscope has a particular function in that it contains a specific structure and specific mechanisms that when working in concert, enable its function to identify the components of a gas. Applicants are effectively arguing that a nucleic acid and a gas chromatograph are analogous because they can be used as a research tool. However the gas chromatograph has specific, credible and substantial utility in identifying the presence or absence of agents such as chlorine in crude oil samples that has a known effect – toxicity to catalysts used in gasoline refining even in very low concentrations (footnote 5). With respect to the use of nucleic acids to detect the presence or absence of a polymorphism, the specification does not teach or suggest what the effect of the presence or absence of a polymorphism would incur whereas the presence or absence of chlorine (as determined by a gas chromatograph) directly correlates to catalyst toxicity. Thus the nucleic acids can only be used to detect sequences that themselves have no specific and substantial utility. See MPEP 2107.01

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

[...] Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.

- *Probes/Primer Source*

- The response asserts that the nucleic acids can be utilized as probes for other molecules or as a source for primers. This argument was thoroughly reviewed but was not found persuasive because the specification does not teach or suggest that function or gene or promoter to be correlated to the claimed nucleic acid leaving a skilled artisan without direction as to that which the primer or probes would amplify or identify.

- In the 1st- 2nd paragraph of page 8; applicants argue that the claimed nucleic acid can isolate nucleic acid molecules such as the "promoter of the gene corresponding to that claimed nucleic acid molecule" (2nd paragraph). The specification fails to correlate any gene to the claimed nucleic acid or to SEQ ID NO: 1, or any promoter to the sequence. Without knowing the function of the gene, isolating the promoter of the unknown, uncharacterized gene does not represent a substantial utility. This argument is circular because the reason one would identify the promoter is to express the gene to determine what the nucleic acid does. Detecting or determining the promoter of a sequence that has no specific and substantial utility does not exemplify a specific or substantial utility. (See utility guidelines)

- In the 2nd paragraph of page 8 and the 1st paragraph of page 9; applicants argue that the claimed nucleic acid can "initiate a chromosome walk" (p. 8), that it is "useful starting point for a walk to isolate a promoter active in wheat plants" (p. 9). A 'starting point' or starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case no gene or promoter has been specifically correlated to SEQ ID NO: 1 so the mere detection of itself on a region on the chromosome does not result in a useful final product because the function of the protein encoded by the nucleic acid in that region has not been described nor has the polynucleotide been associated with a disease or some other immediately useful property.

- In the 3rd paragraph of page 9; applicants argue that there is "no requirement for exclusive utility" with respect to other molecules also being used for the same purpose as the chromosome walks; "[s]uch an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.* hitting golf balls." The argument is not persuasive because in the golf club case - a golf club has a specific and substantial utility and therefore an improved golf club for instance, would as well. This utility is directly dependent upon the structure of the golf club and the materials of which it is composed. In the instant case, no specific or substantial utility has been established for the claimed nucleic acid. A golf club is not structurally or functionally analogous to the nucleic acid of the present invention. Thus to be able to hit a golf ball in an effective and controlled manner because of the structure and

composition of the club is a real world context of use, and is immediately apparent with no further experimentation needed to determine its use, whereas the unique combination of the nucleotides within a nucleic acid molecule determines its specific function or activities; however in the instant case, further experimentation is required to determine its function. The asserted utilities for the present invention do not take advantage of the particular combination of nucleic acids in the present invention but rather rely on properties common to all nucleic acids. The utility is therefore considered non-specific.

Substantial Utility

- In the 2nd- 3rd paragraph of page 10; applicants argue the utilities have been recognized by the public in that such utilities of the claimed nucleic acid and ESTs because of the occurrence of the "growth of a multi-mullion dollar industry in the Unites States" (p. 10, 2nd paragraph) proving their "commercial value" (3rd paragraph). This argument was thoroughly reviewed but was not found persuasive because potentially any fragment has commercial value to someone, but this is not specific in any way to SEQ ID NO: 1.

Credible Utility

- With regard to applicants' comments regarding credible utility (last paragraph of p. 10 to end of p. 11), while the disclosed utilities for the present invention are credible, they are not specific and not substantial. The asserted utilities do not take advantage of the specific structure, sequence, or properties of the claimed SEQ ID NO: 1, but rather are uses common to all polynucleotides. The utility of an invention must satisfy three criteria in order to be valid: the utility must be credible, specific, and substantial. Examiner is not challenging the credibility of the instant invention. The assertion that the utility of the present invention is credible (and examiner does not suggest that such uses are not credible), does not in any way affect the fact that the utility is also non-specific and not substantial.

- In the 1st paragraph of page 12; applicants argue that the enablement requirements of the claim have been met for reasons that "it is a well-established law that 'the enablement

requirement is met if the description enables any mode of making and using the invention.' *John Hopkins University v. CellPro*, 152 F3d 1342, 1361, 47 U.S.P.Q2d 1705, 1719 (fed. Cir. 1998)". The argument for this rejection is not found persuasive for the same reasons as set forth above. The claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. As such, one skilled in the art clearly would not know how to use the claimed invention.

NEW GROUNDS FOR REJECTION

Claim Rejections - 35 USC § 112

- The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid encoding a plant protein or a fragment thereof comprising SEQ ID NO: 1. SEQ ID NO: 1, per se meets the written description provisions of 35 USC 112, first paragraph. However, the specification only describes a nucleic acid that is not a full-length open reading frame, but an EST, which has the sequence of SEQ ID NO: 1. The nucleic acid sequence of SEQ ID NO: 1 appears to be a fragment of a larger protein since it was isolated from a *Triticum aestivum* cDNA library. The specification has provided no teachings as to a function for a protein encoded by isolated SEQ ID NO: 1 and provides no description of the remainder of the coding sequence of which SEQ ID NO: 1 is a fragment. The structure of the full-length coding sequence is not taught by the specification yet the claims encompass such. There is no description of what type of protein SEQ ID NO: 1 might be encoding. Consequently,

the specification does not support applicant's possession of a nucleic acid encoding a plant protein comprising a nucleic acid sequence of SEQ ID NO: 1 at the time of filing.

In addition, claims such as claims 1 and 11-13 in the recitation of " ***a*** nucleic acid sequence of SEQ ID NO: 1" (claims 1, 13) and "***a*** nucleic acid sequence selected from the group of SEQ ID NO: 1" (claims 11, 12) encompass sequences of any magnitude and/or content that comprise at least a minimum of a two base pair sequence of SEQ ID NO: 1. The recitation "***a*** complement" in claims 11 and 12 does not limit the claims to the full complement of SEQ ID NO: 1, thus the claims encompass sequences not described by the specification. The specification describes that which is termed 'complement' within the claims is the following (emphasis added):

> A nucleic acid molecule is said to be the "complement" of another nucleic acid molecule if they exhibit complete complementarity. As used herein, molecules are said to exhibit "complete complementarity" when every nucleotide of one of the molecules is complementary to a nucleotide of the other. [...] Departures from complete complementarity are therefore permissible, as long as such departures do not completely preclude the capacity of the molecules to form a double-stranded structure. Thus, **in order for an nucleic acid molecule or fragment of the present invention to serve as a primer or probe it need only be sufficiently complementary** in sequence to be able to form a stable double-stranded structure" (specification, p. 18, lines 7-25).

Thus the claims 13 and 14 in addition to claims 11 and 12 are not limited to "the [full] complement" of SEQ ID NO: 1 because of the recitation "a complement thereof" (as described above) describes the nucleic acid molecules of the instant invention as not requiring completely complementary but needing only to be sufficiently complementary. The claims are directed to encompass gene sequences, and complements of sequences of SEQ ID NO: 1, corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. An example of the large variable genus are the fragments of the following nucleic acid GenBank entries from a variety of organisms that are encompassed by the claims:

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- AQ402486 Homo sapiens, positions 377-396 align 100% with positions 8-27 of SEQ ID NO: 1;
- BQ603510 Sus scrofa (pig), postions 10-29 align 100% with positions 7-26 of SEQ ID NO: 1;
- DR37H4t Danio rerio (zebrafish), positions 4-22 align 100% with positions 139-157 of SEQ ID NO: 1;
- BX513761 Mus musculus (house mouse), positions 420-402 align 100% with positions 7-25;
- BF542512 Rattus norvegicus (Norway rat), positions 286-214 align 100% with positions 196-214 of SEQ ID NO: 1; and

- AW871780 Xenopus laevis (African clawed frog), positions 378-396 align 100% with positions 127-145 of SEQ ID NO: 1.

The above specific regions align 100% with regions of SEQ ID NO: 1, thereby "comprising **a** sequence of SEQ ID NO: 1" and "complements thereof". Therefore, as seen above the breadth of the claims is very large to which there is insufficient description in the specification. Claim 2 requires the plant protein or fragment thereof to be a what protein, however the specification does not disclose the content of the sequence that differentiates between a wheat protein and a non-wheat protein; what determines a fragment to specifically be of a wheat protein versus a non-wheat protein.

Claims 13- 15 recite substantially purified nucleic acid molecules having between 95% and 100% sequence identity to SEQ NO: 1 or a complement thereof (claim 13), a substantially purified nucleic acid having between 99% and 100% sequence identity with SEQ ID NO: 1 (claim 14), and a substantially purified nucleic acid according to claim 15 wherein the nucleic acid comprises a region having a single nucleotide polymorphism. The specification, however, does not disclose the content of this polymorphic region, thus claiming a function without structure. These claims read on a very broad and highly variable genus of nucleic acid molecules which includes variants, homologs, and mutants of SEQ ID NO: 1, with either retained or altered function.

Beyond providing the sequence data for SEQ ID NO: 1, however, the specification provides no teaching or guidance which correlates the sequence of SEQ ID NO: 1 to its function, which amino acids in the protein encoded by SEQ ID NO: 1 are critical to its function, or how to modify SEQ ID NO: 1 to obtain any specific homolog, mutant, or variant. It is not clear which positions with SEQ ID NO: 1 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 1. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule is functionally equivalent to SEQ ID NO: 1. The claims provide for a large genus of nucleic acids that include undisclosed genes, partial genomic sequences, mutants, variants, and homologs of SEQ ID NO: 1, however the single disclosed structural feature of SEQ ID NO: 1 does not provide for a substantial portion of the claimed genus.

While one of skill in the art could argue that the claimed genus of polynucleotides is adequately described since one can isolate these polynucleotides by sequence comparison using

the polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone should not be used to determine a protein's function and that small amino acid changes can drastically change the function of a polypeptide. Bork [Genome Research, 10: 398-400 (2000)] teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. [PNAS 92; 6743-6747 (1995)] teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* were found to be hydroxylases once tested for activity. Seffernick et al. [J. Baceriol. 183 (8); 2405-2410 (2001)] teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. [Science 282: 1315-1317 (1998)] teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydroxylase and as few as six amino acid substitutions can transform a hydroxylase to a desaturases. The genus of polynucleotides comprised by the claim is a large variable genus, which can potentially encode proteins of diverse functions. The specification only discloses a single species of the genus, i.e. the polynucleotide of SEQ ID NO: 1, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed with respect to claims 1, 2 and 11-15.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of a substantially purified nucleic acid molecule consisting of the sequence of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997);
>
> *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide a written description of the invention of claims 1, 2 and 11-15. This is a rejection based on a lack of WRITTEN DESCRIPTION.

Response to Arguments

- In the 2nd paragraph of page 13 to the 2nd paragraph of page 15; applicants argue that the specification has disclosed "not only the nucleotide sequence required by the claims (*i.e.*, SEQ ID NO: 1) but also several variations including and directed to the claimed nucleic acid molecules" (p. 13, 2nd paragraph). Applicants further point to the description of vectors, the libraries from which the nucleotides were purified, contemplation of labels or markers for facilitated detection, site directed mutagenesis, *etc.* that encompass describing the possible variations of SEQ ID NO: 1, that are read on by the claims. This argument has been thoroughly reviewed but is not found to be persuasive because the specification does not reflect possession

of mutants, variants, or homologs of SEQ IDNO: 1 from any source by merely disclosing the sequence of SEQ ID NO: 1 and general descriptions on how to alter it. For example, placing SEQ ID NO: 1 in a vector does not reflect possession of mutants or variants of SEQ ID NO: 1. Further site direct mutagenesis describes how to obtain the mutant or variant but this is not the same as describing what the variant is.

- In the 3rd paragraph of page 15; applicants argue that the "Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure" wherein applicants have disclosed the "common structural features" of SEQ ID NO: 1 by providing its nucleic acid sequence. As such, applicant states that "the respective common structural feature (the nucleotide sequence of SEQ ID NO: 1) is shared by every nucleic acid molecule in this claimed genus" (bridging paragraph of pp. 15-16) thus those sequences of 95%-100% identity are taught by the specification. Applicants argument is not found convincing because the while one of skill in the art could argue that the claimed genus of polynucleotides is adequately described since one can isolate these polynucleotides by sequence comparison using the polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone cannot be used reliably to determine a protein's function and that small amino acid changes can drastically change the function of a polypeptide. The specification teaches SEQ ID NO: 1, a 332 bp sequence, yet fails to describe a reading frame that would encode a protein or protein fragment as desired by the claim. Assuming argumendo the reading frame was known, the 1%-5% difference in sequence not disclosed can destroy the protein or protein fragment to be encoded. Any percent difference can greatly alter structure and/or function of the resulting peptide. Bork [Genome Research, 10: 398-400 (2000)] teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. [PNAS 92; 6743-6747 (1995)] teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* were found to be hydroxylases once tested for activity. Seffernick et al. [J. Baceriol. 183 (8); 2405-2410 (2001)] teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. [Science 282: 1315-1317 (1998)] teaches that as few as

four amino acid substitutions can convert an oleate 12-desaturase into a hydroxylase and as few as six amino acid substitutions can transform a hydroxylase to a desaturases. The genus of polynucleotides comprised by the claim is a large variable genus, which can potentially encode proteins of diverse functions. The specification only discloses a single species of the genus, i.e. the polynucleotide of SEQ ID NO: 1, which is insufficient to put one of skill in the art in possession of all attributes and features of all species within the genus. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

- The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite due to the lack of clarity in the claim language "nucleic acid molecule that encodes a plant protein or fragment thereof comprising a nucleic acid sequence" (lines 1-2). It is unclear whether the "fragment thereof" refers to a fragment of the encoded protein or a fragment of the isolated nucleic acid molecule. As such claim 15 is rendered vague and indefinite due to dependency from claims 13.

Claim 2 is vague and indefinite due to the lack of clarity in the claim language "wherein the plant protein or fragment thereof is a wheat protein or fragment thereof" (lines 1-2). As stated above, that which defines "fragment thereof", a wheat protein fragment or a fragment of the nucleic acid that encodes a wheat protein, is unclear.

Claims 11-14 are vague and indefinite as to what is meant therein by the limitation "complement thereof"(line 2 of claims 11 and 13; line 3 of claims 12 and 14). A possible interpretation is that the complement must be of the same length and be the full and exact complement of the recited sequence. Another interpretation is that any complement is meant including those with less than 100% complementarity, such as 90%, 50%, or even 10%.

Clarification of the metes and bounds of the claim is requested via clearer claim wording. Claim 15 is rendered vague and indefinite due to dependency from claims 13.

Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by the GenBank accession number BE428765 (26-July-2000).

The GenBank accession number BE428765 is a mRNA from the wheat plant Triticum turgidum and comprises a nucleic acid sequence of SEQ ID NO: 1 (for example, nucleic acid positions 46-251 of SEQ ID NO: 1). The aligned sequence segment of positions 98-303 is 100% identical to SEQ ID NO: 1. A nucleic acid molecule or a fragment of nucleic acid positions 46-251 of SEQ ID NO: 1 would be a complete complement to the accession number positions 98-303, therefore the instant accession number anticipates the claimed nucleic acid. In addition, please note that even a minimum of a two base pair sequence anticipates claims 1 and 2 due to the claim language "fragment". With respects to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and depends on what one is comparing it to. Therefore the GenBank accession number BE42765 anticipates claims 1, 2 and 11-15 as a nucleic acid molecule comprising or consisting of a nucleic acid sequence of SEQ ID NO: 1.

- Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by the GenBank accession number AI861202 (19-July-1999).

The GenBank accession number AI861202 is a mRNA from the plant Zea mays and comprises a nucleic acid sequence of SEQ ID NO: 1 (for example, nucleic acid positions 314-332 of SEQ ID NO: 1. The aligned sequence segment of positions 169-187 is 100% identical to

SEQ ID NO: 1. A nucleic acid molecule or a fragment of nucleic acid positions 314-332 of SEQ ID NO: 1 would be a complete complement to the accession number nucleotide positions 169-187, therefore the instant accession number anticipates the claimed nucleic acid. In addition, please note that even a minimum of a two base pair sequence anticipates claims 1 and 2 due to the claim language "fragment". Claim 2 is anticipated by any fragment, being that the "plant protein or **fragment** thereof is **a** wheat protein or **fragment thereof**" (lines 1-2, emphasis added); any fragment such as two base pairs can be a fragment of a wheat protein. With respects to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and depends on what one is comparing it to. Therefore the GenBank accession number AI861202 anticipates claims 1, 2 and 11-15 as a nucleic acid molecule comprising or consisting of **a** nucleic acid sequence of SEQ ID NO: 1.

- Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by products O3628 and O4378 of the 1993 SIGMA Chemical Catalog.

In The 1993 Sigma Chemical Catalog product O3628 is a 7-mer oligonucleotide of poly dT nucleotides and product O4378 is a 4-mer oligonucleotide of poly dA nucleotides, both of which are 100% identical to a nucleic acid sequence of SEQ ID NO: 1. It is noted that these oligonucleotides are fragments in length as required for instant claims 1 and 11-14, and/or are at least about 95%-100% (and 99%-100%) identical to poly T segments or their complementary respective poly A segments of the instantly claimed nucleic acids. They thus anticipate instant claims 1 and 11-14 via segments therein which are poly T segments or poly A segments present in the SEQ ID NO: 1 (nucleic acid positions 7-15 and 189-193 respectively). In addition, please note that even a single base anticipates claims 1 and 2 due to the claim language "fragment". Claim 2 is anticipated by any fragment being that the "plant protein or **fragment** thereof is **a** wheat protein or **fragment thereof**" (lines 1-2, emphasis added); any fragment such as two base pairs can be a fragment of a wheat protein. With respects to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and depends on what one is comparing

it to. Therefore the O3628 and O4378 products anticipate claims 1, 2 and 11-15 as a nucleic acid molecule comprising or consisting of a nucleic acid sequence of SEQ ID NO: 1.

Objections to the Specification

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code in the specification in the following place: a) page 5, lines 18 and20; and b) page 28, lines 19-21. See MPEP § 608.01.

Conclusion

- MAINTAINED: The rejection of claims 1, 2 and 11- 15 is reiterated and maintained under 35 U.S.C. 101/112 – utility.
- MAINTAINED: The rejection of claims 13- 15 is reiterated and maintained under 35 U.S.C. 112, first paragraph – written description.
- NEW: Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 112, first paragraph – written description.
- NEW: Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 112, second paragraph.
- NEW: Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by the GenBank accession number BE428765.
- NEW: Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by the GenBank accession number AI861202 (19-July-1999).
- NEW: Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by products O3628 and O4378 of the 1993 SIGMA Chemical Catalog.
- Objection to the specification.

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The central **Fax number is (703) 872-9306.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (571) 272-0749. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Sitton, can be reached at (571) 272-0752. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (571) 272-0518, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 29, 2004
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Jehanne S. Sitton
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1/29/04